dependence on the responsiveness of the RWD holder. Further, the findings underscore limited feasibility for assessing outcomes in anti-diabetic drugs without database linkage, suggesting the need for improved RWDs in Europe.

PRM28

ASSESSING THE COMPLETENESS OF MATERNITY DATA RECORDING IN UK PRIMARY AND SECONDARY CARE

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OBJECTIVES: To compare the completeness of maternity data from a primary care database, The Health Improvement Network (THIN), and a secondary care database, Hospital Episodes Statistics (HES). **METHODS:** From 1998-2009, 2,649 pregnancies were identified from one practice in THIN. A group of 15,166 patients in the same practice was linked to secondary care data from HES and 3,285 pregnancies were identified from this population. The completeness of recording for maternity variables within each dataset was compared. **RESULTS:** Maternal age was recorded for all pregnancies in both datasets and a measure of social deprivation was recorded for over 95% of pregnancies in THIN and HES. Ethnicity recording in THIN was inconsistent with 56.4% missing or unknown, whilst in HES it was recorded for 75.1% of pregnancies. In THIN, 0.2% of pregnancies had data on the number of babies compared to 94% of pregnancies in HES. In both datasets, less than 25% of pregnancies had the number of previous pregnancies recorded. In HES, over 60% of pregnancies contained data on birth weight, sex of the baby and mode of delivery compared to fewer than 7% of pregnancies in THIN. Gestational age at birth was recorded for less than half of pregnancies in both THIN and HES. **CONCLUSIONS:** These maternity data are better recorded in HES than in THIN, suggesting possible benefits from linking the two data sources – primary care provides clinical information e.g. medical conditions and prescriptions, whilst secondary care provides data on pregnancy and birth outcomes. These findings are currently limited to one practice. Future work includes examining the baby's records in THIN and HES for further data, assessing other variables, such as non-live birth outcomes, and expanding the analysis to a larger dataset of THIN-HES linked practices.

PRM29

SUPRAPUBIC PROSTATECTOMY (SP) VERSUS TRANSURETHRAL ENDOSCOPIC RESECTION OF PROSTATE (TURP): HOSPITALIZATION OUTCOMES AND COSTS OF BENIGN PROSTATIC HYPERPLASIA USING A PRUBLIC DATABASE (DATASUS) IN BRAZIL

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OBJECTIVES: To evaluate the costs and outcomes of two Benign Prostatic Hyperplasia (BPH) surgical procedures available in the public health care system in Brazil. **METHODS:** A 3-year longitudinal analysis (2009 to 2011) of an anonymized government administrative database (Inpatient Information System - SIH/DATASUS) was performed. The study cohort comprised all BPH hospitalization registries (ICD10 D299 and N40) from male patients and aged 40 years and over. Patients were uniquely identified by the following parameters: date of birth, postal code, gender and ethnicity. Deterministic registry matching was applied. Costs were reported in 2012 Brazilian currency (1BRL=0.52USD). Outcomes assessed were reoperation rates, average in-hospital length-of-stay (in days), and need for intensive care unit (ICU). Descriptive statistics [i.e., average, standard deviation (SD) and proportions] summarized studied data. **RESULTS:** A total of 48,750 patients with average age of 68.3±8.6 were identified within 3 years of analysis. 21,747 patients were submitted to SP (total cost BRL27.9 million) and 27,003 to TURP (total cost BRL22.0 million). There were different proportions of surgical types among Brazilian regions, SP and TURP, respectively: North (N) 69.5% vs. 30.5%, Northeast (NE) 57.7% vs. 42.3%, Central West (CE) 43.3% vs. 58.7%, South (S) 41.3% vs. 58.7% and Southeast (SE) 32.6% vs. 67.4%. SP was linked with longer in-hospital length-of-stay (6.45±5.29) versus TURP (3.95±4.31) and also with an increased proportion of procedures requiring ICU 4.2% and 2.6%. The rate of reoperation was 0.5% in SP and 1.8% in TURP patients. **CONCLUSIONS:** SP compared with TURP procedure was linked with more costs to public health care system in Brazil, a higher need for ICU utilization and increased days of hospitalization. Nevertheless, reoperation rates following SP were lower than TURP. A higher number of SP procedures in different Brazilian regions may be related to availability/access/discrepancies in the treatment of BPH, lack of technology and under diagnose.

PRM30

HOSPITALIZATION REGISTRY AND COSTS OF BENIGN PROSTATIC HYPERPLASIA PATIENTS (BPH) BASED ON A PUBLIC DATABASE (DATASUS) IN BRAZIL

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OBJECTIVES: To evaluate hospitalization registry and disease costs of benign prostatic hyperplasia (BPH) patients in the public health care system in Brazil. **METHODS:** A 3-year longitudinal analysis (2009 to 2011) of an anonymized government administrative database (Inpatient Information System - SIH/DATASUS) was performed. Patients with at least one BPH registry (ICD10 D291/N40) were uniquely identified by the following parameters: date of birth, postal code, gender, and ethnicity and followed over the analysis period to find events associated with BPH. Patients with prostate/bladder cancer were excluded. Deterministic registry matching procedures were applied. Costs were reported in 2012 Brazilian currency (1BRL=0.52USD). Outcomes assessed were rehospitalization rates, age and ethnicity distribution. Descriptive statistics [i.e., average, standard deviation (SD) and proportions] summarized studied data. **RESULTS:** A total of 55,123 patients (average 68.4±8.8 years) were identified throughout the analysis. Age distribution was 15.6% ≤59 years, 74% 60-79 and 10.4% ≥80. Ethnicity distribution was: 36.5% whites, 24.8% Latin, 3.8% Black, 1.1% others and 33.7% without information. Most patients were admitted to hospital for BPH surgical procedures (88.4%). Percentage of a second hospitalization due to BPH was 9.9%. Other 2.5% required three or more hospitalizations. Percentage of total hospitalizations and total costs for BPH associated events were: Acute Urinary Retention (AUR): 2.6% and 1.9%, Urinary Tract Infection (UTI): 2.6% and 1.3%, Urethral Stenosis: 1.9% and 1.0%, Infection and Inflammation: 0.8% and 0.3%, Renal Failure 0.7% and 1.2% and Others: 2.4% and 2.8%. Total cost was BRL60,7 million (BRL20million yearly) with an average cost of BRL1,100/patient/year, with age group variations of BRL889 in 40-49 years to BRL1,147 in 70-79 years. Total cost with BPH associated events was BRL5,1million. **CONCLUSIONS:** In Brazil, BPH patients are more frequently hospitalized in age group 60-79 with a 3-year rehospitalization rate reaching 12.4%. AUR and UTI represented the most frequent and costly BPH associated events.

PRM31

ASSESSMENT OF ADOPTION OF UNITED STATES PRESCRIBING GUIDELINES FOR DABIGATRAN IN A REAL WORLD POPULATION

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OBJECTIVES: Dabigatran is indicated to reduce stroke/ systemic embolism risk in patients with non-valvular atrial fibrillation (AFIB). Post approval, there has been much focus on dabigatran safety. Thus, we evaluated dabigatran real world use and safety in the United States in the context of approved labeling relating to safety. **METHODS:** A retrospective evaluation was conducted of de-identified, pharmacy/medical claims in patients with a new dabigatran prescription claim during 11/2010-08/2011 and continuous eligibility of 12 months prior and 4-months after initiation of treatment. Demographic/clinical characteristics of patients, prescriber specialty, and adoption of approved labeling recommendations (renal function testing, drug interactions, and dosage recommendations) were assessed. **RESULTS:** A total of 1,424 patients, mostly males (61.5%), 73±11 years old, received a dabigatran dose of 150mg BID (93.8%), prescribed primarily by a cardiologist (60.7%). In regards to label guidance, 1090 (77%) patients had a claims history for AFIB, 19.2% were exposed to medications that increase the serum concentration of dabigatran, and 20.2% were exposed to medications listed as inhibitors of dabigatran metabolism. Renal function assessment within the prior year was evident in 22.8% of patients (11.3% in pts >75 years old), and over 4 months of f/u in 12.3% (6.1% in pts >75 years old). Additionally, only 48.8% of patients with a creatinine clearance <30 mL/min received 75 mg BID. **CONCLUSIONS:** Despite specific dabigatran labeling recommendations, a high percentage of prescribers are not following the guidance for: indications; dosage adjustment for interacting drugs, renal function, or age; or, renal function monitoring, which may adversely affect stroke or bleeding outcomes. Ongoing review and action on dabigatran prescribing and monitoring to optimize safe clinical outcomes in a real world population are needed.

PRM32

DEVELOPMENT OF A POST-MARKETING REQUIREMENTS (PMR) DATABASE

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OBJECTIVES: Post-marketing surveillance for adverse effects has become an essential element of new drug and medical devices development in the European Union and the USA. The objective of this study is to present an overview of the content of a database that gathers details of Post-Marketing Requirements (PMRs), i.e., studies requested by the following regulatory agencies: European Medicines Agency (EMA, EU); the Food and Drug Administration (FDA, USA); and the Haute Autorité de Santé (HAS, France). **METHODS:** All drug approvals published by the EMA, the FDA, and the HAS between January 1, 2005 and December 31, 2011 were reviewed to retrieve PMRs. The information was categorized as follows: product description (brand name, INN, indication, etc.); application details; PMR details; and information source. **RESULTS:** For the FDA, we reviewed 763 original approvals and 944 supplements and included, respectively, 201 and 110 drugs approved with PMRs. For the EMA, we reviewed 349 marketing authorizations and included 38 files with PMRs. For the HAS, 3674 opinions were published with only 174 opinions with PMRs. Many HAS requests were long-term follow-up studies. About 43% of the PMRs requested by the FDA were pediatric studies. At present, the EMA also requires pediatric studies but under a Pediatric Investigation Plan (PIP). Since 2005, 21 PIPs have been requested. No matter which agency is reviewed, all kinds of indications are covered by the PMRs, e.g., treatment of sepsis, asthma, depressive disorder, etc. **CONCLUSIONS:** This project will be a unique source of centralized information about PMRs requested in Europe and in the USA. It will be useful to observe the trends in studies requested, to anticipate the demands, and to integrate the studies as early as possible in the product development process. The Post-Marketing Requirements database will be available online in an independent website, with access by subscription.

PRM33

REAL WORLD EVIDENCE: PROMISE AND PITFALLS OF REAL WORLD DATA

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OBJECTIVES: Clinical trials remain the gold standard for proving efficacy but restrictive enrolment criteria and overly controlled study environments limit generalizability. Increasingly, payers and health care providers are interested in real world evidence to support the case for pharmaceutical innovations. We review